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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,729	10/09/2001	Mark M. Goodman	70-01	7821

23713 7590 06/16/2003

GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/16/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/974,729

Applicant(s)

GOODMAN ET AL.

Examiner

Michael G. Hartley

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 8-11 and 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7, 12, 13 and 25-38 is/are rejected.
- 7) ☒ Claim(s) 39-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Election/Restrictions

The election of the species wherein X is CHCHBr, Y is H, R' is CH₂(CH₂)₄F and R'' is CH₃ is acknowledged.

After no prior art was found to reject the claims based on applicant's elected species, a new species within the scope of the invention was elected by the examiner to which the claims were searched and examined. This species the same at the elected species, except that R' is the first formula (the N2S2 chelate shown) and X is CHCHI (as in claim 6) and to include CHCHBr. Consequently, claims 3-5, 8-11 and 14-24 are withdrawn as not reading on the elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhar (US 5,413,779).

Kuhar discloses a compound having the structure set forth in column 3, line 50. This formula is within the scope of the formula in claims 25-28, wherein the trimethyltin moiety is the leaving group, "L" as claimed and Y as claimed is H. The compounds are labeled with ¹²³I, see column 5. Further, it is noted that the recitation that an element is "capable of" is not a positive limitation and does not constitute a limitation in any patentable sense. See *In re Hutchison*, 69 USPQ 138. The compositions disclosed therefore would include all of the components of the claimed kit, as "kit" in the preamble does not specifically add any definable limitations. Also, the intended use "for the rapid synthesis of..." is not given patentable weight, since the claims are examined only to what is contained in the kit and not to the intended use of the kit or what may be formed after some manipulation of the kit.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 7, 12, 13 and 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kung (US 6,241,963) in view of Davies (US 6,013,242).

Kung discloses tropane derivative compounds of formula I in column 5. This formula may be substituted to yield compounds, which are very similar to those claimed. For example, wherein said formula Q is A₂, Z is CO₂R₁ (R₁ is methyl) provides compounds that are similar to the claimed compounds, wherein R' is the first listed formula, Y is H and R'' is methyl. The only difference being that the X substituent as claimed, i.e., the para-substitution of the phenyl is different in the formula disclosed by Kung as compared to the claimed compounds. The compounds are radiolabeled for methods of imaging, see column 3. Kits for the preparation of the compounds are taught in column 7 and the precursors used to prepare the compounds include leaving groups on reagents capable of being radiolabeled at the same positions. Note, the groups Q and R₁ may be methyl, thereby corresponding to claims 37 and 38.

Kung fails to teach compounds having the same "X" substitution on the phenyl ring as claimed.

Davies discloses tropane derivative compounds formula I in column 4. These tropane compounds are analogous to those disclosed by Kung and have the same properties and utilities. The compounds radiolabeled for methods of imaging, see column 4. Davies teaches that the phenyl substitution at the para position includes those as claimed, i.e., CHCH₃I (as in present claim 6) or CHCH₃-radiohalogen, e.g., CHCH₃*Br (claims 33-38), see column 4 and compound 11 in column 21. The other substitutions of the tropane compounds are similar to those of Kung. Davies specifically teaches that the modification the tropane compounds at the aryl (phenyl) moiety, i.e., "X" position as claimed provides the

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advantage of producing compounds which are 800 times more potent as compared to known tropane compounds, see column 3, lines 40+. Thus, Davies clearly teaches the advantage of modifying tropane compounds to include a moiety which is within the scope of "X" as claimed.

It would have been obvious to one of ordinary skill in the art to modify the compounds disclosed by Kung to include a moiety encompassed by "X" as claimed, such as, CHCHI, because Davies teaches that modification of analogous tropane compounds to include such a group at this position produces compounds that are over 800 times more potent than other known compounds. Since Davies clearly teaches that the modification of tropane compounds analogous to Kung should include moiety encompassed by "X" and Kung teaches similar moieties at the "X" position, one of ordinary skill in the art would have been motivated to modify the Kung tropane compounds to include a moiety such as CHCHI at the "X" position to increase the potency of the compounds. The inclusion of such a moiety, as taught by Davies, as the moiety on the phenyl substituent of the tropane compounds disclosed by Kung would arrive at compounds encompassed by the claims.

Claim Objections

Claims 25-28 are also objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 25-28 fail to further limit their base claims, since these claims provide a kit comprising a compound having a formula which is not within the scope of the formula in the base claim. Also, the base claim is directed to a "compound" while the dependent claim is drawn to a "kit for...synthesis of a radiolabeled compound." That is, it is not a kit containing the compound of claim 1, but a kit that can be used to make the compound of claim 1. These kit claims do not require the particulars of the base claim, since the particulars of the base claim are only provided by an intended use recitation in the dependent claims, therefore these claims do not properly further limit the base claim, since they do not actually further define the "compounds" of the base claim.

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All wabl Subject Matter

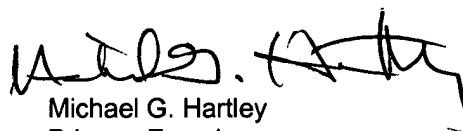
Claims 39-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 39-42 are free of the art of record since the prior art fails to disclose or suggest compounds having the structure as set forth in these claims, namely the combination of X and R' as set forth therein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
June 13, 2003